DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 352

[Docket No. 78N–0038]

RIN 0905–AA06

Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Tentative Final Monograph; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the tentative final monograph for over-the-counter (OTC) sunscreen drug products (58 FR 28194, May 12, 1993) to include only the 15 active ingredients for which United States Pharmacopeia (U.S.P.) monographs currently exist or for which interest in developing U.S.P. monographs has been expressed. This proposal is part of the ongoing review of OTC drug products conducted by FDA. FDA is reopening the comment period until August 22, 1994 to give interested parties an opportunity to comment on the proposed amendment to the tentative final monograph.

DATES: Written comments or objections by August 22, 1994; writen comments on the agency's economic impact determination by August 22, 1994.

ADDRESSES: Written comments or objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 12, 1993 (58 FR 28194), FDA published a notice of proposed rulemaking, in the form of a tentative final monograph, for OTC sunscreen drug products. In proposed § 352.10 (21 CFR 352.10) of the May 12, 1993, tentative final monograph (58 FR 28194 at 28295), the agency proposed the following ingredients in Category I (i.e., generally recognized as safe and effective):

(1) Aminobenzoic acid,
(2) Cinoxate,
(3) Diethanolamine methoxycinnamate,
(4) Digalloyl trioleate,
(5) Dioxybenzone,
(6) Ethyl 4-[bis(hydroxypropyl)] aminobenzoate,
(7) Glyceryl aminobenzoate,
(8) Homosalate,
(9) Lawsone with dihydroxyacetone,
(10) Menthyl anthranilate,
(11) Octocrylene,
(12) Octyl methoxycinnamate,
(13) Octyl salicylate,
(14) Oxybenzone,
(15) Padimate O,
(16) Phenylbenzimidazole sulfonic acid,
(17) Red petrolatum,
(18) Sulisobenzone,
(19) Titanium dioxide,
(20) Trolamine salicylate.

The agency also stated that, in order for a sunscreen ingredient to be included in the final monograph, it would be necessary for the ingredient to be adequately characterized and for these standards to be published in an official compendium (58 FR 28194 at 28284). The agency noted that only a few Category I sunscreen active ingredients are standardized and characterized for quality and purity and are included in official compendia (i.e., aminobenzoic acid, cinoxate, dioxybenzone, oxybenzone, and titanium dioxide). The agency suggested that interested parties should develop with the U.S.P. appropriate standards for the quality and purity of sunscreen active ingredients that are not already included in official compendia (i.e., diethanolamine methoxycinnamate, digalloyl trioleate, ethyl 4-[bis(hydroxypropyl)] aminobenzoate, glyceryl aminobenzoate, homosalate, lawsone with dihydroxyacetone, menthyl anthranilate, octocrylene, octyl methoxycinnamate, octyl salicylate, phenylbenzimidazole sulfonic acid, red petrolatum, sulisobenzone, and trolamine salicylate). The agency pointed out that if such standards are not established, ingredients without available public standards would not be included in the final monograph.

In letters dated January 13, 1994 (Ref. 1), the agency reminded two manufacturers associations (representing many OTC drug and cosmetic manufacturers of sunscreen-containing drug products) that all sunscreens ingredients must have a U.S.P. monograph before being included in the final monograph for OTC sunscreen drug products. FDA encouraged the associations to work with the U.S.P. in establishing the necessary monographs. Stating that the agency believes that some of the proposed Category I ingredients are no longer used for formulating sunscreen drug products, the agency questioned whether manufacturers would be working to establish U.S.P. standards for these ingredients. The agency asked for comment regarding which ingredients companies would be working to establish U.S.P. monographs.

The associations replied jointly in a letter dated February 15, 1994 (Ref. 2). The letter stated that, in addition to the five ingredients FDA listed as having established U.S.P. monographs, a sixth ingredient, padimate O, also has a U.S.P. monograph. The letter further stated that industry members currently intend to work with U.S.P. to develop compendial monographs for the following nine ingredients:

(1) Diethanolamine,
(2) Octocrylene,
(3) Octyl methoxycinnamate,
(4) Octyl salicylate,
(5) Homosalate,
(6) Menthyl anthranilate,
(7) Phenylbenzimidazole sulfonic acid,
(8) Sulisobenzone,
(9) Trolamine salicylate.

No interest was expressed in the remaining ingredients (i.e., digalloyl trioleate, ethyl 4-[bis(hydroxypropyl)] aminobenzoate, glyceryl aminobenzoate, lawsone with dihydroxyacetone, and red petrolatum).

References

(1) Letters from W. E. Gilbertson, FDA, to J. D. Cope, Nonprescription Drug Manufacturers Association, and E. E. Kavanaugh, Cosmetic, Toiletry and Fragrance Association, Comments No. LET110 and LET111, respectively, in Docket No. 78N–0038, Dockets Management Branch.

(2) Letter from E. E. Kavanaugh, Cosmetic, Toiletry and Fragrance Association, and J. D. Cope, Nonprescription Drug Manufacturers Association, to W. E. Gilbertson, FDA, Comment No. C301, in Docket No. 78N–0038, Dockets Management Branch.

II. The Agency's Tentative Conclusions

Based upon the apparent lack of interest in establishing U.S.P. monographs for digalloyl trioleate, ethyl 4-[bis(hydroxypropyl)] aminobenzoate, glyceryl aminobenzoate, lawsone with dihydroxyacetone, and red petrolatum, the agency tentatively concludes that these ingredients will not be included in the final monograph for OTC sunscreen drug products and should be deleted from the tentative final monograph. Therefore, the agency is amending the tentative final monograph for OTC sunscreen drug products to remove these five ingredients. The agency is also withdrawing the warnings and directions proposed in §§ 352.52(c)(2)

and 352.52(d)(3) for lawsone with dihydroxyacetone.

FDA has examined the impacts of the amendment of the tentative final monograph under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this amendment of the tentative final monograph is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the amendment of the tentative final monograph is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order. The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency is not aware of any currently marketed sunscreen drug products that contain any of the ingredients being withdrawn from the monograph. Accordingly, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency is reopening the comment period until August 22, 1994 to allow interested persons the opportunity to comment specifically on the proposal in this document to include only the 15 active ingredients listed. The agency is also inviting public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC sunscreen drug products. Types of impact may include, but are not limited to, costs associated with reformulating, relabeling, or repackaging. Comments regarding the impact of this rulemaking on OTC sunscreen drug products should be accompanied by appropriate documentation. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before August 22, 1994, submit to the Dockets Management Branch (address above) written comments or objections regarding this proposal. Written comments on the agency's economic impact determination may be submitted on or before August 22, 1994. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments and objections are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments and objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 352

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 352 (as proposed in the Federal Register of May 12, 1993 (58 FR 28194)), be amended as follows:

PART 352—SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 352 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

§ 352.10 [Amended]

2. Section 352.10 Sunscreen active ingredients is amended by removing paragraphs (d), (f), (g), (i), and (q) and reserving them.

§ 352.20 [Amended]

3. Section 352.20 Permitted combinations of active ingredients is amended by removing paragraphs (a)(2)(iv), (a)(2)(vi), (a)(2)(vii), (a)(2)(ix), and (a)(2)(xvii) and reserving them.

§ 352.52 [Amended]

4. Section 352.52 Labeling of sunscreen drug products is amended by removing paragraphs (c)(2) and (d)(3) and reserving them.

Dated: May 18, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

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